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Risk factors and protective strategies for hypotony following preserflo microshunt implantation

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The PreserFlo MicroShunt (PMS) is a minimally invasive surgical device for glaucoma management. However, postoperative hypotony remains a significant complication. This retrospective cohort study analyzed 471 eyes to evaluate the efficacy of PMS implantation in reducing intraocular pressure (IOP) and medication dependency, as well as to identify risk factors associated with hypotony. The median IOP decreased significantly from 19 mmHg preoperatively to 10 mmHg three months postoperatively, with the median medications score dropping to zero. Postoperative hypotony occurred in 18.7% of the cases. Multivariate analysis identified preoperative IOP ≥ 25 mmHg (odds ratio (OR): 2.01, 95% confidence interval (CI): 1.00–4.02, $p = 0.049$) and medication scores ≥ 5 (OR: 2.12, 95% CI: 1.13–3.96, $p = 0.019$) as significant risk factors for hypotony, while axial length ≥ 25.5 mm (OR: 0.19, 95% CI: 0.09–0.39, $p < 0.001$) and intraluminal suture stenting (OR: 0.08, 95% CI: 0.03–0.25, $p < 0.001$) were significantly protective. Importantly, intraluminal suture stenting mitigated the risk of hypotony without compromising the short-term surgical outcomes. These findings emphasize the need for careful patient selection and the potential of intraluminal suture stenting as an effective intraoperative strategy to improve the safety and outcomes of PMS implantation.

Keywords Glaucoma, Hypotony, PreserFlo microshunt, Intraluminal suture stenting, Risk factors

Glaucoma remains a leading cause of irreversible blindness globally, affecting millions of people and posing substantial public health challenges[1,2]. Its prevalence is projected to increase significantly, underlining the urgent need for effective therapeutic strategies. While medical therapy and laser procedures constitute the first-line treatment for reducing intraocular pressure (IOP), surgical interventions are indispensable for patients with advanced or refractory glaucoma. Among surgical options, trabeculectomy has long been the gold standard[3–5], yet its invasive nature and associated complications have spurred interest in less invasive glaucoma surgeries.

One promising innovation is the PreserFlo MicroShunt (PMS) (Santen Pharmaceutical Co., Ltd., Osaka, Japan), a device designed to achieve significant IOP reduction with a less invasive approach than traditional surgeries[6]. PMS, fabricated from a biocompatible polymer, diverts aqueous humor from the anterior chamber to the subconjunctival space, forming a bleb. PMS implantation has been reported to be associated with lower rates of bleb-related complications and reinterventions than trabeculectomy[7–9]. However, postoperative hypotony remains an encountered complication after PMS implantation, with reported rates ranging from 1.7 to 39% in the literature[10]. During the early postoperative period, it has been reported that hypotony is significantly more common with PMS implantation than with trabeculectomy[11]. While transient hypotony often resolves without surgical intervention[12], persistent hypotony can lead to irreversible damage, emphasizing the need to elucidate the associated risk factors.

This study aims to assess the efficacy of PMS implantation in reducing IOP and glaucoma medications during the early postoperative period, while also identifying risk factors associated with hypotony following PMS implantation.

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Results

Patient demographics and baseline characteristics

A total of 471 eyes of 372 patients that underwent PMS implantation were included in this study. The median age of the participants was 74 (interquartile range; IQR, 65–80) years, and 45.9% were female. The glaucoma subtypes were distributed as follows: primary open-angle glaucoma (POAG, 60.9%), pseudoexfoliative glaucoma (XFG, 23.6%), and secondary glaucoma excluding pseudoexfoliative glaucoma (SG, 15.5%). Table 1 summarizes the demographic and baseline characteristics of the enrolled patients.

Postoperative changes and incidence of postoperative complications

The median (IQR) IOP significantly decreased from 19 (15–24) mmHg at baseline to 7 (5–10) mmHg at 1 day, 9 (8–11) mmHg at 1 month, 10 (8–12) mmHg at 2 months, and 10 (9–13) mmHg at 3 months after PFM implantation (all, $p < 0.001$). The median (IQR) medication scores also significantly decreased from 4 (3–5) at baseline to 0 (0–0) at 1 month ($p < 0.001$), and 0 (0–0) at 3 months after PFM implantation ($p < 0.001$) (Fig. 1). Postoperative hypotony occurred in 88 eyes (18.7%). Among these cases, 36 eyes (7.6%) had a shallow anterior chamber, 78 eyes (16.6%) had choroidal detachment, and 1 eye had hypotony maculopathy. Additionally, 29 eyes (6.2%) had both a shallow anterior chamber and choroidal detachment. Within three months after PMS implantation, surgical interventions were required in 7 eyes (1.5%) for severe hypotony, in 10 eyes (2.1%) for elevated IOP, and 3 eyes (0.6%) for malignant glaucoma.

Risk factors for hypotony

Table 2 shows the results of the univariate and multivariate analyses to identify the risk factors associated with hypotony following PMS implantation. Univariate analysis identified several risk factors associated with hypotony after PMS implantation. Advanced age (≥80years) was significantly associated with hypotony (odds ratio (OR): 3.07, 95% confidence interval (CI): 1.90–4.96, $p < 0.001$). Preoperative IOP ≥ 25mmHg (OR: 2.66, 95% CI: 1.62–4.35, $p < 0.001$) and preoperative medication scores of ≥ 5 (OR: 2.06, 95% CI: 1.29–3.31, $p = 0.002$) were also significant risk factors. The glaucoma subtype, specifically XFG versus POAG, showed a significant association (OR: 2.73, 95% CI: 1.61–4.61, $p < 0.001$). Conversely, an axial length ≥ 25.5 mm (OR: 0.22, 95% CI: 0.12–0.40, $p < 0.001$) and intraluminal suture stenting (OR: 0.11, 95% CI: 0.03–0.27, $p < 0.001$) were associated with a significantly reduced risk of hypotony.

In the multivariate analysis, after adjusting for confounders, preoperative IOP ≥ 25mmHg (OR: 2.01, 95% CI: 1.00–4.02, $p = 0.049$) and preoperative medication scores of ≥ 5 (OR: 2.12, 95% CI: 1.13–3.96, $p = 0.019$) remained independent risk factors for hypotony. Axial length ≥ 25.5 mm (OR: 0.19, 95% CI: 0.09–0.39, $p < 0.001$)

Characteristics	Value
Age (years), median (IQR)	74 (65, 80)
Sex, Female (%)	217 (45.9)
Laterality, Right (%)	234 (49.7)
Preoperative BCVA, logMAR, median (IQR)	0.15 (0.00, 0.52)
Preoperative IOP, mmHg, median (IQR)	19 (15, 24)
Preoperative medication scores, median (IQR)	4 (3, 5)
Central corneal thickness, μm, median (IQR)	518 (492, 544)
Axial length, mm, median (IQR)	25.20 (23.85, 26.76)
Mean deviation, dB, median (IQR)	− 16.28 (− 22.49, − 9.99)
Glaucoma subtype, number of eyes (%)	
Primary open angle glaucoma	287 (60.9)
Pseudoexfoliative glaucoma	111 (23.6)
Secondary glaucoma excluding pseudoexfoliative glaucoma	73 (15.5)
Previous surgery, number of eyes (%)	
Outflow reconstruction surgery	80 (17.0)
Filtering surgery	18 (3.8)
Cataract surgery	273 (58.0)
Vitreous surgery	41 (8.7)
Surgery, number of eyes (%)	
PMS stand-alone	341 (72.2)
PMS combined with cataract surgery	131 (27.8)
Additional procedures with PMS, number of eyes (%)	
Posterior end of the tube fixation	329 (69.9)
Intraluminal suture stenting	121 (25.7)

Table 1. Demographic and baseline characteristics of the 471 enrolled patients. Values are presented as median (IQR) or number (%). *IQR* interquartile range, *BCVA* best-corrected visual acuity, *IOP* intraocular pressure, *PMS* PreserFlo MicroShunt.

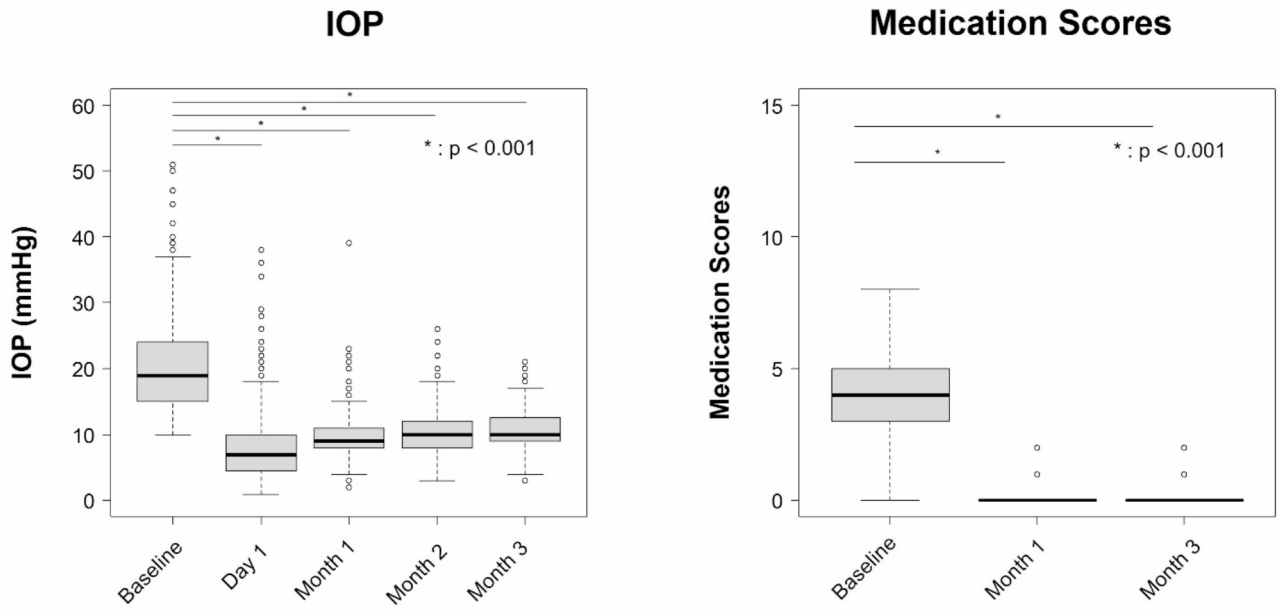

Fig. 1. Changes in intraocular pressure (IOP) and medication scores. Left: Boxplot showing intraocular pressure (IOP) at baseline, postoperative day 1, and months 1, 2, and 3. A significant reduction in IOP was observed at all time points compared with baseline (all $p < 0.001$, Steel's multiple comparison test). Right: Boxplot showing medication scores at baseline, month 1 and 3 months. Medication scores were significantly reduced at months 1 and 3 compared with baseline (all $p < 0.001$, Steel's multiple comparison test). In both boxplots, the horizontal lines within each box represent the median values, the boxes indicate the interquartile range (IQR), and the whiskers represent the range excluding the outliers. Individual points represent outliers beyond 1.5 times the IQR.

Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*p*	OR (95% CI)	*p*
Age ≥ 80 years (vs. < 80 years)	3.07 (1.90–4.96)	< 0.001	1.58 (0.76–3.26)	0.219
Female (vs. male)	0.93 (0.58–1.47)	0.748	0.78 (0.42–1.45)	0.441
Preoperative BCVA (logMAR) ≥ 0.155 (vs.< 0.155)	1.38 (0.87–2.20)	0.177	1.47 (0.78–2.75)	0.233
Preoperative IOP ≥ 25mmHg (vs.< 25 mmHg)	2.66 (1.62–4.35)	< 0.001	2.01 (1.00-4.02)	0.049
Preoperative Medication Scores ≥ 5 (vs.< 5)	2.06 (1.29–3.31)	0.002	2.12 (1.13–3.96)	0.019
CCT ≥ 500 μm (vs.< 500 μm)	0.83 (0.51–1.39)	0.478	0.74 (0.39–1.39)	0.346
Axial Length ≥ 25.5 mm (vs.< 25.5 mm)	0.22 (0.12–0.40)	< 0.001	0.19 (0.09–0.39)	< 0.001
Glaucoma subtype: XFG (vs. POAG)	2.73 (1.61–4.61)	< 0.001	1.50 (0.69–3.27)	0.309
SG (vs. POAG)	1.47 (0.73–2.81)	0.265	0.82 (0.33–2.08)	0.677
History of outflow reconstruction surgery (vs. none)	1.22 (0.66–2.16)	0.519	1.02 (0.46–2.27)	0.952
History of filtering surgery (vs. none)	1.71 (0.54–4.68)	0.318	0.98 (0.23–4.19)	0.980
History of cataract surgery (vs. none)	3.17 (1.87–5.60)	< 0.001	2.33 (0.78–6.98)	0.131
History of vitreous surgery (vs. none)	0.45 (0.13–1.15)	0.134	0.28 (0.06–1.44)	0.128
PMS combined with cataract surgery (vs. PMS Stand-alone)	0.43 (0.23–0.77)	0.007	0.79 (0.24–2.61)	0.693
Posterior end of the tube fixation (vs. none)	0.75 (0.46–1.23)	0.251	1.27 (0.67–2.43)	0.462
Intraluminal suture stenting (vs. none)	0.11 (0.03–0.27)	< 0.001	0.08 (0.03–0.25)	< 0.001

Table 2. Univariate and multivariate analyses to identify the risk factors associated with hypotony following PMS implantation. *IQR* interquartile range, *BCVA* best-corrected visual acuity, *IOP* intraocular pressure, *XFG* Pseudoexfoliative Glaucoma, *POAG* Primary Open Angle Glaucoma, *SG* Secondary glaucoma excluding Pseudoexfoliation Glaucoma, *PMS* PreserFlo MicroShunt, *OR* Odds Ratio, *CI* Confidence Interval.

and intraluminal suture stenting (OR: 0.08, 95% CI: 0.03–0.25, $p < 0.001$) were significant protective factors. Other variables, such as age ≥ 80years, glaucoma type, history of cataract surgery (i.e., pseudophakic eyes), and combination of PMS implantation with cataract surgery were not statistically significant in the multivariate analysis.

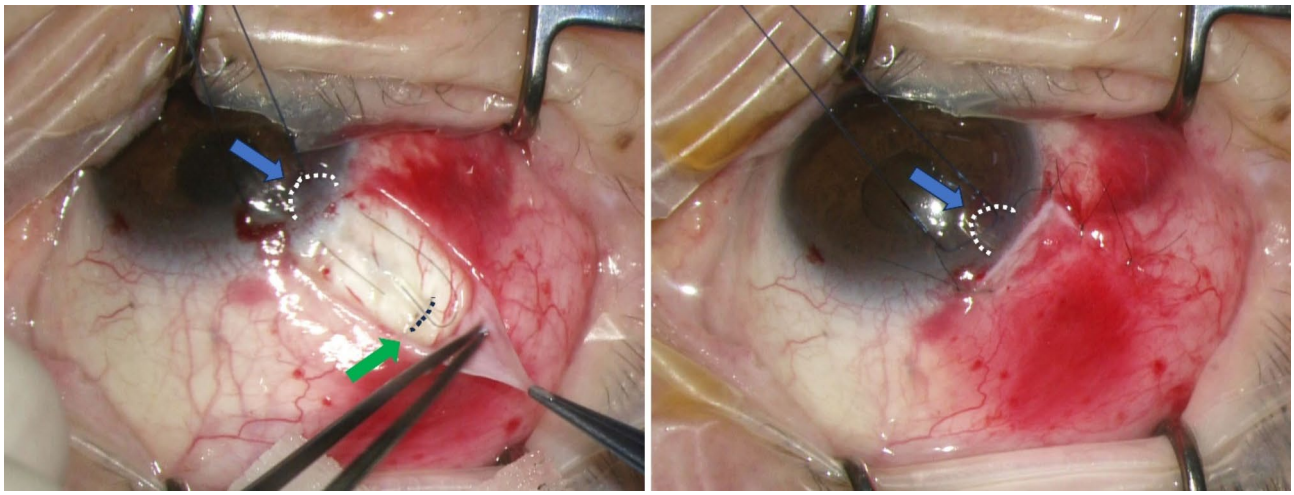

Fig. 2. Intraoperative images of the intraluminal suture stenting. Left: Intraoperative image during the procedure. The green arrow and the black dotted line indicate the posterior end of the tube fixation to prevent the tube from rising or bending. A 9 – 0 or 10 – 0 nylon suture was inserted into the outer lumen of the PMS and the other side was passed through the cornea and placed beneath the conjunctiva. The blue arrow and white dotted curve highlight the suture loop on the cornea. Right: Image at end of surgery. The blue arrow and white dotted curve highlight the suture loop on the cornea, with the majority of the suture positioned beneath the conjunctiva. The suture can be easily removed by pulling the loop.

	Intraluminal suture stenting ($N=121$)	Non-intraluminal suture stenting ($N=350$)	p value
Preoperative IOP	20.0 (16.0, 24.3)	19.0 (15.0, 23.5)	0.081
Day 1 IOP	12.0 (8.8, 14.0)	6.0 (4.0, 8.0)	< 0.001
Month 1 IOP	10.0 (8.0, 11.0)	9.0 (8.0, 11.0)	0.951
Month 2 IOP	10.0 (8.0, 12.0)	10.0 (9.0, 12.0)	0.427
Month 3 IOP	10.0 (8.8, 12.0)	11.0 (9.0, 13.0)	0.159
Preoperative medication scores	4 (3, 5)	4 (3, 5)	0.820
Month 1 medication scores	0 (0, 0)	0 (0, 0)	0.861
Month 3 medication scores	0 (0, 0)	0 (0, 0)	0.269

Table 3. Intraocular pressure changes with and without intraluminal suture stenting. p value is calculated by Wilcoxon rank-sum test. *IOP* intraocular pressure.

Impact of intraluminal suture stenting on IOP and medication scores

Figure 2 shows the intraoperative images of intraluminal suture stenting. The impact of intraluminal suture stenting on IOP control is shown in Table 3. IOP and medication scores were compared with and without intraluminal suture stenting. Preoperative IOP was comparable between the two groups, with a median (IQR) of 20.0 (16.0-24.3) mmHg in the stenting group and 19.0 (15.0-23.5) mmHg in the non-stenting group. On postoperative day 1, the median (IQR) IOP was significantly higher in the stenting group than in the non-stenting group (12.0 (8.8–14.0) mmHg vs. 6.0 (4.0–8.0) mmHg, $p<0.001$). However, at 1, 2, and 3 months postoperatively, there was no significant difference in IOP between the two groups. Medication scores were similar between the two groups at all time points.

Discussion

This study demonstrated that PMS implantation effectively reduced the IOP and medication burden in patients with glaucoma during the first three months postoperatively. The median IOP significantly decreased from 19 mmHg at baseline to 10 mmHg at three months postoperatively, whereas the median medication score dropped to zero within the same period, underscoring the efficacy of the procedure in achieving sustained IOP control with reduced pharmacological dependence. In contrast, postoperative hypotony was observed in 18.6% of the cases. Risk factors for hypotony included preoperative IOP ≥ 25mmHg and medication scores ≥ 5, whereas longer axial length (≥ 25.5 mm) and intraluminal suture stenting emerged as significant protective factors.

To the best of our knowledge, this is the first study to comprehensively investigate the risk factors associated with hypotony following PMS implantation. Although risk factors for hypotony after traditional filtering surgery have been reported, the identified risk factors for developing hypotony and its associated complications include young age[13–18], myopia[13–18], preoperative use of carbonic anhydrase inhibitors[15], male gender[13,16], primary filtering surgery[16–18], and higher preoperative intraocular pressure[18,19]. In this study, a higher preoperative

intraocular pressure and greater medication scores were identified as significant risk factors for postoperative hypotony. Greater medication scores may indicate increased preoperative use of carbonic anhydrase inhibitors.

Interestingly, longer axial length is a significant protective factor for hypotony following PMS implantation. Myopia has been considered a risk factor for hypotony, not only following traditional filtering surgery, but also following PMS implantation[20]. After XEN Gel Stent implantation, which is a 6 mm long, 45 μm wide hydrophilic tube of porcine gelatine, a longer axial length (over 24.3 mm) predisposes the eye to the development of hypotony[21]. In this study with a large number of cases, a longer axial length was significantly protective against hypotony following PMS implantation. The aqueous humor outflow through the PMS follows the Hagen-Poiseuille equations[22,23]. In eyes with a longer axial length, the larger ocular volume results in a more gradual pressure change, potentially reducing the risk of postoperative hypotony. Further studies are needed to elucidate this discrepancy.

Recent studies have revealed the efficacy of intraluminal suture stenting for PMS implantation in preventing postoperative hypotony[20,24–27]. The stent can be safely removed after surgery, resulting in a controlled IOP reduction. Notably, surgical success and long-term IOP control were not compromised by stent placement[20,24,26]. In our study, intraluminal suture stenting also significantly reduced the incidence of postoperative hypotony and made no difference in the reduction of IOP and medication scores for up to 3 months. Optimal timing for stent removal remains a topic of discussion, however, intraluminal suture stenting should be considered, especially in patients with a higher preoperative intraocular pressure or greater medication scores.

This study had several limitations. First, its retrospective design introduces the potential for selection bias and limits its ability to establish causality. Since the use of intraluminal suture stenting was started at some point, it was not randomized. Second, the follow-up period in this study was limited to three months. Although this has allowed for the assessment of early postoperative outcomes, long-term data on the durability of IOP control and the long-term influence of intraluminal suture stenting are lacking. Future research should focus on validating these results and assessing the long-term outcomes to enhance the safety and efficacy of PMS implantation.

In conclusion, this study identified key factors influencing hypotony following PMS implantation. Higher preoperative intraocular pressure and greater medication scores were significant risk factors, while longer axial length and intraluminal suture stenting were protective factors. Importantly, intraluminal suture stenting mitigated the risk of hypotony without compromising the short-term surgical outcomes. These findings emphasize the need for careful patient selection and the potential of intraluminal suture stenting as an effective intraoperative strategy to improve the safety and outcomes of PMS implantation.

Materials and methods

Study design

This multicenter retrospective cohort study was included 476 consecutive eyes that underwent PMS implantation between August 2022 and May 2024 at Kyoto Prefectural University of Medicine and affiliated institutions. Ethical approval was obtained from the institutional review board (ERB-C-1909-2) and the study adhered to the tenets of the Declaration of Helsinki. Informed consent of surgery was obtained from all the participants.

We included all patients aged ≥ 18 years with a previous diagnosis of glaucoma, having an IOP above the target despite maximal medical treatment, and receiving PMS implantation. We excluded patients who were lost to follow-up before the three-month postoperative visit.

Data were obtained via a review of the medical records of the patients, and included the following data points: 1) patient demographics (i.e., age, sex, preoperative best-corrected visual acuity, preoperative IOP, preoperative medication scores, central cornea thickness, axial length, mean deviation, glaucoma subtypes, and previous surgery), 2) surgical procedure performed (PMS stand-alone or PMS combined with cataract surgery), and 3) additional procedures with PMS (posterior end of the tube fixation, intraluminal suture stenting). In all patients, IOP was measured using a Goldmann applanation tonometer and the medication scores were calculated based on the number of glaucoma medications used, that is, single medical agents were scored as 1, combination medical agents were scored as 2, and oral acetazolamide medication was scored as '1 point' per tablet.

In this study, hypotony was defined as an IOP < 5 mmHg associated with complications such as a shallow anterior chamber, choroidal detachment, and hypotony maculopathy. Cases with lower intraocular pressure and no symptoms were not classified as hypotony.

Surgical procedures

All surgeries were performed by three experienced glaucoma surgeons (H.M., K.M., and M.U.) using a standardized PFM implantation technique. After placing a corneal traction suture, the surgical procedure began with a superior fornix-based conjunctival peritomy. After meticulous dissection of Tenon's capsule, mitomycin-C (MMC) was applied to the exposed sclera using the soaked sponges (0.4 mg/mL) for 5 min. After copious irrigation with saline solution, the path for PMS insertion into the anterior chamber was established using a dedicated double-step knife. The knife was inserted at a point 3 mm from the limbus, reaching a 4.5 mm depth marker. This design ensured that the fin was positioned 3 mm from the limbus. The fins of the tube were securely seated and fixed within the sclera. After verifying the aqueous humor drainage from the distal end of the PFM, in some cases, the posterior end of the tube was fixed with 10 – 0 nylon (Mani, Inc., Tochigi, Japan) to prevent it from rising or bending. Subsequently, the tenon and conjunctiva were sutured using 10–0 nylon, followed by a subconjunctival injection of dexamethasone (1.65 mg) to complete the procedure. Postoperatively, the patients were instructed to use corticosteroids and antibacterial eye drops four times daily.

During the study period, an additional step was introduced in the surgical procedure to prevent postoperative hypotony. From January 2024, a 9 – 0 (Mani, Inc., Tochigi, Japan) or 10 – 0 nylon suture was inserted into the PMS lumen in all patients to restrict aqueous flow during the early postoperative period. The selection of nylon suture diameter was determined by institutional availability rather than being individualized for each patient.

The stent was generally removed two weeks after surgery. However, in cases where the intraocular pressure (IOP) remained below 10 mmHg, the surgeon opted to delay removal by an additional one to two weeks based on clinical judgment. Due to concerns regarding the risk of infection, all patients in this study underwent stent removal within one month.

Statistical analysis

All statistical analyses were performed using the R software version 4.3.3 (R Foundation for Statistical Computing, Vienna, Austria). Continuous variables were expressed as medians with interquartile ranges (IQR), and a P-value < 0.05 was considered statistically significant. Steel's multiple comparison test was used for within-group comparisons of the preoperative and postoperative IOP and medication scores. Comparisons between the groups were conducted using the Wilcoxon rank-sum test.

Univariate and multivariate analyses were conducted to identify risk factors for hypotony following PMS implantation. Univariate and multivariate analyses were performed using a logistic regression model, and ORs and 95% CIs were calculated.

Data availability

The datasets generated in the current study are available from the corresponding author upon reasonable request.

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Author contributions

H.M., K.M., and M.U.: conception and design; H.M., K.M., and Y.O.: collection and assembly of data; H.M., K.M., K.Y., Y.I., M.U., and C.S.: data analysis and interpretation; H.M., K.M., K.Y., M.U., and C.S.: writing the manuscript. All authors have reviewed the manuscript.

Declarations

Competing interests

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Additional information

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